

**510(k) Summary**

**ArthroCare Corporation  
ArthroCare® System 2000  
ArthroCare® Orthopedic Electrosurgery System  
ArthroCare® Bipolar Loop**

K 0 2 0 8 3 2

**General Information**

**Submitter Name/Address:** ArthroCare Corporation  
680 Vaqueros Avenue  
Sunnyvale, CA 94085-2936

**Establishment Registration Number:** 2951580

**Contact Person:** Valerie Defiesta-Ng  
Director, Regulatory Affairs

**Date Prepared:** March 13, 2002

**Device Description**

**Trade Name:** ArthroCare System 2000  
ArthroCare Orthopedic Electrosurgery  
System  
ArthroCare Bipolar Loop

**Generic/Common Name:** Electrosurgical Device and Accessories

**Classification Name:** Electrosurgical Cutting and Coagulation  
Device and Accessories (21 CFR  
878.4400)

**Predicate Devices**

ArthroCare System 2000, ArthroCare  
Orthopedic Electrosurgery System, and  
ArthroCare Bipolar Loop K011634

**Product Description**

The ArthroCare Wands are bipolar, single use, high frequency electrosurgical devices designed for specific indications in neurosurgical, spinal, and urological procedures.

## **Intended Use**

### **ArthroCare System 2000**

- The ArthroCare System 2000 is indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in orthopedic, arthroscopic, spinal, and neurosurgical procedures.

### **ArthroCare Orthopedic Electrosurgery System**

- The ArthroCare Orthopedic Electrosurgery System is indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in in orthopedic, arthroscopic, and spinal procedures.

### **ArthroCare Bipolar Loop**

- The ArthroCare Bipolar Loop is indicated for resection, ablation, and excision, as well as hemostasis of blood vessels in patients requiring endoscopic surgery for general urological procedures including transurethral prostatectomy (TURP), transurethral incisions in the prostate (TUIP), and non-malignant tumors of the bladder wall.

## **Substantial Equivalence**

This Special 510(k) proposes modifications in materials and labeling for the ArthroCare Wands, which were previously cleared under K011634 on June 19, 2001. The indications for use, technology, principle of operation, performance and dimensional specifications, packaging, and sterilization parameters of the Wands remain the same as in the predicate cleared 510(k).

## **Summary of Safety and Effectiveness**

The modified Wands, as described in this submission, are substantially equivalent to the predicate Wands. The proposed modification in materials and labeling are not substantial changes or modifications, and do not significantly affect the safety or efficacy of the devices.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR - 9 2002

Ms. Valerie Defiesta-Ng  
Director  
Regulatory Affairs  
ArthroCare Corporation  
680 Vaqueros Avenue  
Sunnyvale, California 94085

Re: K020832

Trade/Device Name: ArthroCare® System 2000, ArthroCare®  
Orthopedic Electrosurgery System and ArthroCare® Bipolar Loop

Regulation Number: 878.440 and 888.1100

Regulation Name: Electrosurgical Device, Cutting & Coagulation  
& Accessories and Arthroscope and Accessories

Regulatory Class: II

Product Code: GEI and HRX

Dated: January 4, 2002

Received: January 7, 2002

Dear Ms. Defiesta-Ng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

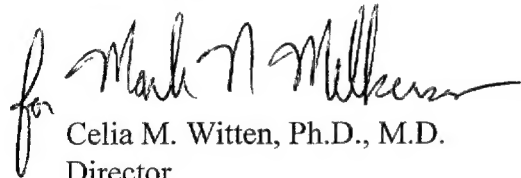
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "for Mark N. Milken".

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use Statement

Device Name: ArthroCare® System 2000  
ArthroCare® Orthopedic Electrosurgery System  
ArthroCare® Bipolar Loop

510(k) Number: K 020832

Indications for use:

### ArthroCare System 2000

- The ArthroCare System 2000 is indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in orthopedic, arthroscopic, spinal, and neurosurgical procedures.

### ArthroCare Orthopedic Electrosurgery System

- The ArthroCare Orthopedic Electrosurgery System is indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in in orthopedic, arthroscopic, and spinal procedures.

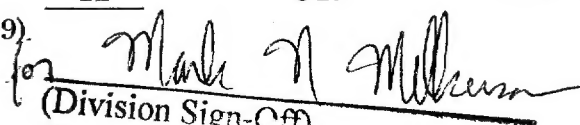
### ArthroCare Bipolar Loop

- The ArthroCare Bipolar Loop is indicated for resection, ablation, and excision, as well as hemostasis of blood vessels in patients requiring endoscopic surgery for general urological procedures including transurethral prostatectomy (TURP), transurethral incisions in the prostate (TUIP), and non-malignant tumors of the bladder wall.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   X   OR Over-the-Counter Use             
(Per 21 CFR 801.109)

  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

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